Establishment Inspection Report	FEI:	**3004056159**
Bayer Medical Care, Inc.	EI Start:	8/14/2018
Pittsburgh, PA 15238-2819	EI End:	8/17/2018

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SUMMARY

Inspection of this medical device manufacturer was conducted as a FY18 work plan assignment per CP 7386.001, Inspection and Field testing of Radiation-Emitting Electronic Products, in accordance with the Radiation Control for Health & Safety Act (RCHSA), under OP ID #99834.
The previous inspection, dated 01/18/2017, was conducted in accordance with Compliance Programs 7382.845B and 7881.011, Inspection of Medical Device Manufacturers, and classified NAI.

This firm manufactures radiological delivery system medical devices, used in diagnostic x-ray operations, under prescription use. During the inspection, a review of the firms Imaging System Interface (ISI) accessory and operational software, manufactured for both injection systems (Arterion and Stellant) was reviewed. At the conclusion of the inspection, it was determined that the ISI does not control the diagnostic x-ray systems used in conjunction with the firm's devices, however the 510(k) for the Arterion injection system does not include the use of the ISI in the indication for use statement (K132928).

Discussion with management included responses to the information provided in the 510(k) and the registration removal for an EPRC product. Management was cooperative and made no refusals, and no FDA Form 483, Inspection Observations, was issued. This inspection is classified as NAI.

ADMINISTRATIVE DATA

Inspected firm: Bayer Medical Care, Inc.

Location:	625 Alpha Dr Pittsburgh, PA 15238-2819
Phone:	412-767-2400
FAX:	
Mailing address:	625 Alpha Dr Pittsburgh, PA 15238-2819
Dates of inspection:	8/14/2018-8/15/2018, 8/17/2018
Days in the facility:	3
Participants:	**Dennis R Hock, Investigator**

On 08/14/2018, credentials were presented and an FDA form 482, Notice of Inspection, was issued to Joseph J. Kridgen, Quality Product Steward. Mr. Kridgen stated that he was the most responsible person at the firm.

HISTORY
This firm operates as Medrad-Bayer, under the Bayer Radiology group-Bayer's Pharmaceuticals Division. According to Mr. Kridgen, this firm is registered with the FDA as Bayer Healthcare. Mr. Kridgen stated that there have been no major changes since the previous inspection.

INTERSTATE (I.S.) COMMERCE
The firm utilizes a third-party logistics warehouse and shipping depot, (b) (4) (formerly (b) (4) located in (b) (4). Products are then further distributed throughout the United States, as well as internationally.

JURISDICTION (PRODUCTS MANUFACTURED AND/OR DISTRIBUTED)
The firm manufactures medical device injection systems, used in radiological theaters, under prescription use.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
On 08/14/2018, credentials were presented and an FDA Form 482, Notice of Inspection was issued to Joseph J. Kridgen, Quality Product Steward. Mr. Kridgen identified himself as the most responsible person at the firm.

During this inspection, Mr. Kridgen, accompanied me throughout the facility. A review of the firm's product design, operation and performance in accordance with EPRC was conducted. The following individuals were present and/or provided relevant information for this report:

Matthew Boyle, Head of Site Quality (O'Hara)
Donna M. Haire, VP Head of Radiology Regulatory Affairs Pharmaceuticals
Troy Jack, Head Regulatory Affairs Operational Excellence
Corey Kemper, Medical Affairs Scientist
Chad Williams, ISI Software Engineer Manager
Allynell Castro, QSA Manager
Jerry Hammack, Senior Engineer Product Analysis
(b) (6), Field Service Technician

On 08/17/2018, during the discussion with management, the following individuals were present:

Joseph J. Kridgen, Quality Product Steward
Matthew Boyle, Head of Site Quality (O'Hara)
Donna M. Haire, VP Head of Radiology Regulatory Affairs Pharmaceuticals (via teleconference)
Troy Jack, Head Regulatory Affairs Operational Excellence
Corey Kemper, Medical Affairs Scientist
Allynell Castro, QSA Manager

All post inspection correspondence should be addressed to Joseph J. Kridgen, Quality Product Steward, and sent to:

Bayer Medical Care, Inc.
625 Alpha Drive
Pittsburgh, PA 15238-2819

MANUFACTURING/DESIGN OPERATIONS

During the inspection, firm management was not aware that the (b) (4) software, used in their Stellant CT injection system, was registered as an EPRC regulated product. Mr. Kridgen stated that the registration is most likely a mistake. Ms. Haire stated to the best of her knowledge, the product was not regulated under EPRC.

I explained to Ms. Haire that if the system is unilaterally controlled from the monitoring device of the injection systems, the product may be considered an EPRC regulated device under diagnostic x-ray systems. I further explained that if the product does fall under EPRC, then the firm would be responsible for performance standards, as well as all applicable filing and documentation.

The firm manufactures two types of injectors. The Stellant is used in conjunction with computed tomography, and the contrast media is injected into the venous system prior to imaging. The Arterion, is used in conjunction with diagnostic x-ray systems, and the contrast media is injected into

the arterial system, primarily for cardiovascular imaging. Both injection systems have an accessory option of implementing an ISI to integrate with either CT or diagnostic x-ray.

During the inspection, a review of the complaints to determine if ARO's would be required, was conducted. Additionally complaints were reviewed to assess the firm's response to possible non-conformances with the ISI's. The design of the device accessory was reviewed along with the individual manuals and labeling. The firm provided multiple OEM manuals of the imaging manufacturers supported to integrate with either injection system. Mr. Williams provided a review of software operations and Mr. Hammack provided information concerning the ISI hardware operations.

During the inspection, it was determined that the (b) (4) does not involve control operations of the imaging systems, but rather on-site control of contrast media dosage for the radiologist. In reviewing the operations of the ISI's for both the Arterion and Stellant injection systems, it was determined that the imaging systems are not controlled through interfacing with the injector. However, after discussing the 510(k) submissions, the Arterion did not include the use of the ISI in the indications of use statement (see discussion with management section of this report).

REFUSALS
No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

During the general discussion with management, I explained that the submission made for the Stellant injection system, was later updated with a supplemental 510(k) (k033881) for use with the ISI. The indications for use statement documents its integration with computed tomography, allowing the injector to communicate with the diagnostic system. However, the submission made for the Arterion (k132928) does not document the use of the ISI in the indications of use statement and no supplemental 510(k) was filed.

Mr. Jack explained within the submission, the firm included all V/V information for the ISI being used in conjunction with the diagnostic x-ray imaging system. Mr. Jack provided all documentation to illustrate that the information was included in the original submission. I explained to Mr. Jack and Ms. Haire that the indication of use statement is what the firm is cleared to use the device for and what all applicable manuals and labeling should document.

Ms. Haire stated the firm received the clearance of the submission and was under the assumption the ISI would have been included, as with the Stellant. I explained to Ms. Haire that unfortunately it was not included in the indications of use and the firm should have contacted ODE to make the correction. Furthermore, the ISI may have been built into the original design, but it's being offered as an accessory to the original design of the device.

Ms. Haire stated the firm is in progress documenting information for the device, which will require an updated submission. She stated that the firm will ensure the indication of use statement is also updated to include the use of the ISI in operation of the device.

I informed Mr. Kridgen that I would be updating the firm's registration to ensure its accuracy and an FDA form 483, Inspection Observations, will not be issued.

EXHIBITS COLLECTED

ATTACHMENTS
1 482, 2 pages

X Dennis R Hock
Investigator
Signed By: 2000754886
Date Signed: 08-28-2018 10:15:13